

REMARKS/ARGUMENTS

Applicants initially express their sincere appreciation for the courtesies extended to applicants, applicants' representative and applicants' counsel during the personal interview at the U.S. Patent and Trademark Office on December 8, 2005. At that time, in addition to a presentation showing the nature and operation of the artificial urinary diversion apparatus of the present invention, the outstanding official action of September 21, 2005, was discussed, and the claims were clarified, particularly with respect to the cross-sectional areas of each section, and the potential for other claim limitations defining locations of the sphincter mechanism, the pump and the controls as compared to the prior art hereagainst.

In response, amendments to claim 29 and the addition of new claims 69 through 106 are respectfully requested. It is believed that the present claims are clearly patentable over all of the prior art cited hereagainst, and reconsideration and allowance of these claims is therefore respectfully solicited. New claims 71-106 correspond to prior claims 30-65, which were only canceled after an indication that claims 66-68 were in condition for allowance was received. That was done to expedite the issuance of a patent thereon. However, since that indication was later withdrawn, and in view of applicants' strong belief that the present claims are all now in condition for allowance, these dependent claims are being resubmitted herewith.

Claims 29, 67 and 68 have been rejected as being unpatentable under 35 U.S.C. § 112, first paragraph. The Examiner contends that the ranges amended within the claims are refined in a manner which is not shown in any drawing or described in the specification. The Examiner thus contends that

the original ranges were described in the specification in paragraphs [0064] and [0065] on pages 13 and 14, but that the refined ranges narrowing them are not so supported. This rejection is respectfully traversed in view of the discussion at the aforementioned personal interview, the above amendments and arguments, and for the further reasons set forth hereinafter.

As was discussed at that personal interview, the specific ranges set forth in these claims are, in fact, set forth in the original specification; i.e., in the original claims filed herein, as well as at the end of paragraphs [0064] and [0065] hereof. It is therefore clear that these limitations are fully supported, and that a rejection under § 112, first paragraph is not in order. Therefore, withdrawal of this rejection is respectfully solicited.

Claims 29, 67 and 68 have been rejected as being anticipated by Guiset under 35 U.S.C. § 102(b). Referring to FIG. 1 of Guiset, the Examiner contends that an artificial urinary diversion system is shown with a urinary bladder 1 having an axial direction comprised of three portions; namely, the first portion being the lowest point in area of reference numeral 21; the second portion is in the middle of reference numeral 5; and the third portion is the topmost portion in the area of reference numeral 30. The first and second portions are said to be smaller in cross-section than the upper portion, and the first portion is said to comprise an outlet 4 and sphincter mechanism 18 for opening and closing at least one outlet to expel liquid therefrom, with the third portion comprising inlet 33 and sphincter mechanism 17 for opening and closing the sphincter. The third portion is said to comprise a second inlet in the area of reference numeral 28 with the sphincter mechanism potentially comprising an anti-reflux valve such as the Bjork-type valve or a STARR-valve in a ring-like shape. The three portions are said to be integrally formed, and the device

shown therein is said to inherently have a three-dimensional shape capable of containing a volume of fluid, and thus a plurality of cross-sectional areas are divided up into portions. Guiset is also said to disclose a cylindrical shape, citing column 4, lines 59-66, which is said to suit the function recited in claim 29 if the values for  $a_1$ - $a_6$  are equal to zero, and the cylinder have a first outline with a shape of a straight line parallel to the longitudinal direction with the other side of the cylinder providing a second outline with a straight line parallel to the longitudinal direction.

In response to applicants' arguments, they are said to all rely upon amendments containing new subject matter, and the prior rejection is said to be valid because even if the number cannot be zero, it is said to be inherent that the numbers can be almost zero, and they could be infinitely small so as to equate to zero since no man-made objects are said to be perfect, and when amplified all surfaces are rough and uneven. This rejection is respectfully traversed in view of the discussion at the aforementioned personal interview, as well as the above amendments and arguments and for the reasons set forth hereinafter.

Turning to the amended claims herein, it is now specifically noted that clear distinctions between the present invention and Guiset are set forth therein. Firstly, and most significantly, all of the claims in this application now specifically not only require that the artificial urinary diversion apparatus hereof include a sphincter mechanism for opening and closing the outlet in the first area and control means for controlling the sphincter mechanism, but that these mechanisms, and most particularly the control means itself, be enclosed entirely within the artificial urinary diversion apparatus hereof; i.e., as defined by the claimed outer surfaces thereof. As is shown in the specification, and as was described

to the Examiner during the aforementioned personal interview, the self-contained device of the present invention preferably includes pump, sphincter and control mechanisms implanted within the device, which can also be controlled from external means as described therein.

Turning to the disclosure in Guiset, the sphincter mechanism for the lower aperture 4 includes an inflatable collar 16. This collar is provided in a normally closed configuration, except during urination periods. Indeed, the specification of the Guiset patent states that "it does not seem absolutely necessary to provide it with a device to induce it to open when it is desired to induce urination." (Col.3, 11.56-59.) The operation of this device is thus entirely controlled by manipulation of a reservoir 23 which is totally external to the artificial bladder shown in this reference. Thus, collar 16, which contains a fluid under a fixed pressure, is opened when the pressure in cavity 2 increases above a predetermined threshold level following an external impulse created upon flexible zone 26 of reservoir 23. In this manner, the fluid 24 contained within reservoir 23 is pressurized. Thus, by pressure being applied to flexible zone 26 by the user pressing upon his abdominal wall 32, fluid 24 is forced to flow from reservoir 23 by means of flexible zone 26 of wall 25, into passage 28. This, in turn, inflates small balloon 27 within cavity 2, overcoming the pressure of lower collar 16, and thereby causing evacuation of this device. It is thus clear beyond question that any device which could conceivably be considered to be equivalent to the pump and/or sphincter control mechanism of applicants' invention is external to the outer surface of the urinary diversion apparatus thereof, as opposed to the requirement of the present claims that the sphincter control mechanism be enclosed entirely within the device itself. Of course, dependent claim 70 also adds the requirement that a pump be

enclosed entirely within the device itself, which further distinguishes over Guiset in this regard.

It is next noted that newly added claim 69 specifically includes the requirement that the at least one largest cross-sectional area of the first portion be larger than the at least one largest cross-sectional area of the second portion, even more clearly distinguishing over the overall shape and structure of prior art such as Guiset. The Guiset reference thus specifically discloses a pseudo-pyramidal shape related to that of a natural bladder, in which the lower portion, as shown in FIG. 1, gradually narrows, and no cross-sectional area in the first area is greater than any largest cross-sectional area in the second or middle area thereof. Applicants have discussed, including in the present specification, the significance of a narrow central area (the second portion) thus permitting the placement of nerves and arteries over that portion without impingement by the device during surgical procedures for implantation thereof. Again, this is clearly not the case in prior art such as Guiset.


It is therefore respectfully submitted that all of the claims now contained in this application possess the requisite novelty, utility and unobviousness to warrant immediate allowance over the prior art cited hereagainst. Therefore, reconsideration and allowance of this application is respectfully solicited. If nothing else, this provides good cause for the entry of these amendments since they clearly reduce the issues presented by this application for purposes of appeal. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By



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